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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/601,245

06/20/2003

Henry Nita

PAT-1505

6687

7590

05/15/2006

Raymond Sun
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EXAMINER

HUH, BENJAMIN

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,245

Applicant(s)

NITA ET AL.

Examiner

Benjamin Huh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/28/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 8, 10-16, 29-33, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-8, 10-16, 29-33, 36-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/20/06 & 6/20/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species I : Claims 1-17 & 29-37 in the reply filed on 11/3/05 is acknowledged.

Applicant's election with traverse of with respect to the distal head, species 3A & B as well as titanium & titanium alloys, with respect to the guidewire aperture location 66b, with respect to the sonic connector elements figure 6 in the reply filed on 2/28/06 is acknowledged. The traversal is on the ground(s) that the election parameters were unclear. This is not found persuasive because the applicant had several phone conversations with the previous examiner to clarify the election as stated in the remarks.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement filed 6/20/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

Claim 12 recites the limitation "the distal head". There is insufficient antecedent basis for this limitation in the claim since the independent claim 10 does not mention a distal head.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 10-16, 29-30, 32, & 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Passafaro et al (US Patent No. 5324255). The Passafaro reference discloses an ultrasound catheter in figures 1-13 comprising an elongate flexible catheter body 12 having a proximal end, a distal end, and a main lumen 100 extending longitudinally therethrough; an ultrasound transmission member 28 extending longitudinally through the main lumen 100 of the catheter body, the ultrasound transmission member 28 having a distal end positioned at the distal end of the catheter body; and a guidewire lumen defined by element 60 extending longitudinally through a portion of the main lumen and terminating in a guidewire port 84 that is closer to the proximal end of the catheter body than to the distal end of the catheter body.

With respect to claim 2, further including a Y-connector 36 connected to the proximal end of the catheter body, with the guidewire port 84 positioned adjacent the Y-connector, see figure 2.

With respect to claim 3, the Passafaro reference also discloses a distal head 104 positioned on the distal end of the catheter body, the distal head made from low-density

material that is rigid and radio-dense and the ultrasound transmission member having a distal end connected to the distal head, see col. 11 lines 10-28.

With respect to claim 10, an elongate flexible catheter body 12 having a proximal end, a distal end, and a main lumen 100 extending longitudinally therethrough; an ultrasound transmission member 28 extending longitudinally through the main lumen of the catheter body, the ultrasound transmission member 28 having a distal end positioned at the distal end of the catheter body; and a guidewire lumen defined by element 60 extending longitudinally through a portion of the main lumen and positioned at about the center of the main lumen, also see figures 1-2, 4-5, & 7.

With respect to claim 11, wherein the guidewire lumen defined by element 60 terminates in a guidewire port 84 that is adjacent the proximal end of the catheter body, see figures 4-5.

With respect to claim 12, wherein the guidewire lumen defined by element 60 is defined by a guidewire tube that is affixed to the distal head 104, see figure 4.

With respect to claim 13, wherein the guidewire lumen defined by element 60 is positioned at about the center of the distal head 104, see figure 4.

With respect to claim 14, the distal head 104 having a bore with a proximal section and a distal section that has an inner diameter that is smaller than the inner diameter of the proximal section of the bore see figures 4, 4a, & 8-9, and a guidewire lumen defined by element 60 extending longitudinally through a portion of the main lumen 100, and into the proximal section of the bore of the distal head, the guidewire lumen terminating before the distal section of the bore of the distal head.

With respect to claim 15, wherein the guidewire lumen defined by element 60 is defined by a guidewire tube 60 that is affixed to the distal head 104, see figure 4.

With respect to claim 16, wherein the guidewire lumen defined by element 60 has a proximal end and a distal end, and wherein the proximal end of the guidewire lumen terminates adjacent the proximal end of the catheter body and is affixed to the catheter body, see figures 1-2 & 4-5.

With respect to claims 29-30, 32, & 36-37, the reference also discloses a sonic connector, proximal end of element 20, positioned at the proximal end of the catheter body for connecting the proximal end of the ultrasound transmission member to an ultrasound generating device at a location where there is maximum longitudinal displacement of the ultrasound generating device and a catheter knob having a bore which surrounds the sonic connector and a portion of the ultrasound transmission member, wherein the sonic connector comprises a proximal section for connection to the ultrasound generating device, and a front portion defining the bore which receives the proximal end of the ultrasound transmission member, the sonic connector having: a distal bore to which the ultrasound transmission member is attached; a central portion having a flat proximal face; a threaded portion extending and spaced-apart from the flat proximal face, the threaded portion attached to the ultrasound generating device including a space between the threaded portion and the flat proximal face, with the face being free of any threads, see col. 6 lines 3-49 and figures 1-2 & 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 & 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passafaro et al (US Patent No. 5324255) as applied in claim 1 and further in view of O'Boyle (US Patent No. 5611807) or Pflueger (US Patent No. 5540656). Now even though Passafaro et al does not explicitly disclose the material of the distal head being of a titanium alloy, the average density being less than 5 g/cm³ and a total mass less than .015 grams attention is directed to Makower or Pflueger. The Makower & Pflueger references teach the use of titanium for effectively transmitting ultrasound energy, therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Passafaro to utilize a titanium distal head with a average density being less than 5 g/cm³ and a total mass less than .015 grams in order to ensure the effective transmission of ultrasonic energy for the procedure and to optimize working conditions, also see col. 2 lines 20-29(Makower) & col. 13 lines 27-61 (Pflueger).

Claims 31 & 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passafaro et al (US Patent No. 5324255) as applied in claim 30 and further in view of Nita (US Patent No. 5989208). Now even though Passafaro does not explicitly disclose

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the use of absorbers, more specifically O-rings, attention is directed to Nita. The Nita reference teaches the use of O-rings (232,234) in figure 12 as absorbers, therefore it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the O-rings of Nita in the device of Passafaro in order to minimize vibrations to minimize stress and potential breakage, also see col. 13 line 54 – col. 14 line 7.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BHH

KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons